Exa® PACS/RIS 1.4.30_P1

Customer Release Notes

500-000296A

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Symbols

The following symbols may appear in the product documentation or on the product.

Symbol	Symbol Name	Symbol Description	Standard Number and Name	Symbol Reference Number
	Manufacturer	Indicates the name and address of the manufacturer	ISO 15223-1:2016	5.1.1
	Authorized Representative in the European Economic Area (EEA)	Indicates the Authorized Representative, responsible for the device in the European Economic Area (EEA).	ISO 15223-1:2016	5.1.2
	Date of Manufacture	Indicates the date when the device was manufactured.	ISO 15223-1:2016	5.1.3
	Caution	Indicates information that is important for preventing loss of data or misuse of the software.	ISO 15223-1:2016	5.4.4
	Batch Code	Indicates the full Software Release / Version number	ISO 15233-1:2016	5.1.5
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15233-1:2016	5.1.7
	Catalogue Number	Indicates the manufacturer's catalogue number so that the device can be identified	ISO 15233-1:2016	5.1.6
	Consults instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15233-1:2016	5.4.3
	Prescription Device	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109(b)(1) Prescription Devices	N/A

ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements

Indications for Use

EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.

Training

Users of this software must have received adequate training on its safe and effective use before attempting to operate the product described in this Instructions for Use. Users must make sure they receive adequate training in accordance with local laws or regulations.

Regulatory and compliance

Konica Minolta Healthcare Americas, Inc.
2217 U.S. Highway 70 East
Garner, NC 27529 USA
Tel: 1-800-366-5343

New Features

Summary
• MG Tomos and other restricted SOP classes are no longer DICOM-sent to Alberta Health and other AEs.

Customer Requested Improvements

Summary
• Created a custom invoice form for a customer with fields specific to Alberta, Canada.
• In the Ontario configuration, Exa PACS/RIS now sets the billing class and status of claims to 'Manual review indicator' when required.
• Dispatched exams can now be grouped by dispatch ID for easier order management and billing.
• In the exam screen for technologists, users can now select to apply Tech Start, Tech End, Pause, or Unread status to all studies of the current modality within the current order.
• To prevent scheduling conflicts, selecting a time slot in a Find Slots or Available Slots dialog box now immediately reserves that time slot.

Other Improvements

Summary
• When creating a patient chart, users can now choose to open the Find Slots screen immediately after saving.